K070477

510(K) SUMMARY
(as required by 807.92(c))

Date: January 12, 2007 MAR 0 9 2007

Submitter of 510(k):

Orison Corporation
121 Boone Ridge Dr, Suite 2004
Johnson City, TN 37615
USA

Phone: (423) 282-5919
Fax: (423) 282-6320

Contact Person: Al Sandy

Date of Summary: Date

Trade/Proprietary Name: Orison Embrace System

Classification Name: Transducer, Ultrasonic, Diagnostic

Product Code: ITX
IYO

Intended Use: The Orison Embrace is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of the patients breast when used with an automatic scanning linear array transducer.

Device Description:
The Embrace™ 3D Ultrasound Tomography System is an easy to use diagnostic ultrasound system to be used as an adjunct to mammography for imaging a patient's breast. Ultrasound images are acquired using a general purpose ultrasound system capable of B-mode imaging in conjunction with an automatic scanning concave transducer. The acquired images are reconstructed using 3-D visualization software at a separate clinical review workstation.

Predicate Device: ABUS U-Systems - K052355

Substantial Equivelance:

Orison Corporation claims the proposed device to be substantially equivalent to the device prevuousley cleared by FDA in K052355. Orison Corporation claims this equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles, and physical, operational specifications as compared to the predicate device.

The Orison Embrace System will be used with the Sonix Ultrasound Scanner System manufactured by Ultrasonix Medical Corporation. The Sonix System has already been cleared by the FDA under K061827.

The following non-clinical tests have been completed:

- Acoustic output testing-Meets the standard for Global Maximum Output
- System Verification and Validation Testing (Embrace-TPD-0008 Rev A and Embrace TPR-0006 Rev A) Testing was done using a phantom breast with a known number of cystic masses (6) randomly positioned. All 12 masses were successfully identified.

Results indicate that the Embrace System is substantially equivalent to the listed predicate device.

The similarities and differences between the proposed and predicate devices has been identified and explained in the Cpmparison Matrix which has been included in Section 9 of this submission. Additionally, this matrix is included as an attachment to the 510(k) summary. These differences have no effect on safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 1 2007

Orison Corporation
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K070477
Trade Name: Orison Embrace System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: February 14, 2007
Received: February 20, 2007

Dear Mr. Lehtonen:

This letter corrects our substantially equivalent letter of March 9, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the Orison Embrace Probe intended for use with the Orison Embrace System (Sonix Ultrasound Scanner System and Biomedicom Clinical Review Workstation Software), as described in your premarket notification:

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21

CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Ewa Czerska at (240) 276-3666.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K070477

Device Name: Orison Embrace System

Indications for Use:

The Orison Embrace is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of the patients breast when used with an automatic scanning linear array transducer.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070477

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer

Orison Embrace System

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Breast)		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify)										

N = new indication; **P** = previously cleared

Additional Comments: The Orison Embrace System is intended for B-Mode Ultrasonic imaging of a patient's breast.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seguran F-3

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070477

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer

Orison Embrace Probe

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Breast)		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)										

N = new indication; **P** = previously cleared

Additional Comments: The Orison Embrace Probe is intended for B-Mode Ultrasonic imaging of a patient's breast.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

F-3

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090472